United States District Court

EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
	§	
v.	§	Civil Action No. 4:16-cv-00350-ALM
	§	Judge Mazzant
PROPEL ORTHODONTICS, LLC	§	
	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is Defendant Propel Orthodontics, LLC's Emergency Motion to Modify the Court's Preliminary Injunction Order (Dkt. #318). The Court, having considered the relevant proceedings, finds the motion is denied.

BACKGROUND

Plaintiff, OrthoAccel Technologies, Inc. ("OrthoAccel"), is a medical device company that manufactures dental appliances. In 2008, OrthoAccel developed a prototype hands-free dental device that uses gentle vibrations to accelerate tooth movement when used with orthodontic treatment. This prototype would eventually become the AcceleDent device, which has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extraoral component that generates a vibrational force of 0.25N at 30 Hz. The Activator connects directly to the Mouthpiece, which the patient lightly bites down on for 20 minutes daily to accelerate tooth movement during orthodontic treatment.

On November 5, 2011, the Food and Drug Administration ("FDA") granted 510(k) clearance for AcceleDent as "an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement." A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as a legally marketed device (a

"predicate device") that is not subject to premarket approval. 510(k) clearance is required for Class II devices, but Class I devices are 510(k) exempt. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as a Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Dental implants and braces are examples of Class II devices.

In 2012, OrthoAccel launched its Class II AcceleDent device in the United States to be used in conjunction with orthodontic treatment. In 2013, OrthoAccel launched the AcceleDent Aura ("Aura"), the second generation of AcceleDent, which initially was cleared to be used with braces only. OrthoAccel offers its customers special pricing through its AcceleDent NOW Program ("ADNow"). The ADNow agreements require doctors to offer the AcceleDent device to all patients in their practice and keep a certain number of units in stock. As of January 12, 2017, OrthoAccel had 127 providers signed up for the ADNow program.

Defendant Propel Orthodontics, LLC ("Propel") is also a medical device company that manufactures dental appliances. In January 2016, Propel began marketing a vibratory Class I device designed to help seat clear aligners. Orthodontic patients wear a series of these removable aligners, marketed under names such as Invisalign and ClearCorrect, to gradually straighten their teeth. In March 2016, Propel released the VPro5, which operates at 120 Hz and requires five minutes of daily use to properly seat (i.e., fit better on the teeth) clear aligners. The VPro5 costs significantly less than the OrthoAccel Aura. On July 8, 2016, OrthoAccel's product—the Aura—was cleared for use with clear aligners.

Propel primarily markets the VPro5 through its sales force in a consultative setting. Propel sales representatives originally promoted the VPro5 by telling orthodontists that the device offers

several clinical benefits ("5 Clinical Benefits"). These 5 Clinical Benefits include: (1) more efficient aligner seating, (2) relieves orthodontic pain, (3) accelerates tooth movement, (4) fast tracks retention, and (5) stimulates bone growth and remodeling. Propel's sales force originally marketed the VPro5 as a quicker, cheaper alternative to the AcceleDent device.

In May 2016, OrthoAccel sued Propel, claiming Propel falsely advertised the VPro5's 5 Clinical Benefits in violation of the Lanham Act. On October 26, 2016, the Court entered a preliminary injunction order enjoining Propel from advertising the 5 Clinical Benefits ("Preliminary Injunction Order") (Dkt. #148). On November 25, 2016, Propel filed a notice of appeal of the preliminary injunction (Dkt. #171). On January 30, 2017, Propel filed its opening brief to the Fifth Circuit Court of Appeals. On March 26, 2017, Propel filed this Emergency Motion to Modify the Court's Preliminary Injunction Order (Dkt. #318). On April 10, 2017, OrthoAccel filed its response (Dkt. #329). On April 18, 2017, Propel filed a reply (Dkt. #337).

LEGAL STANDARD

As a general rule, a notice of appeal ousts the district court of jurisdiction over the judgment or order appealed. *Coastal Corp. v. Texas E. Corp.*, 869 F.2d 817, 819 (5th Cir. 1989) (citing *U.S. v. Hitchmon*, 587 F.2d 1357 (5th Cir. 1979)). However, Federal Rule of Civil Procedure 62(c) allows the district court some limited injunctive powers during the pendency of an appeal. Rule 62(c) provides in pertinent part:

> **Injunction Pending Appeal.** When an appeal is taken from an interlocutory or final judgment granting, dissolving, or denying an injunction, the court in its discretion may suspend, modify, restore, or grant an injunction during the pendency of the appeal upon such terms as to bond or otherwise as it considers proper for the security of the rights of the adverse party.

The Fifth Circuit has held that "the authority granted by Rule 62(c) does not extend to the dissolution of an injunction . . . the district court's power to alter an injunction pending appeal is

limited to 'maintaining the status quo.'" *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.*, 73 F.3d 546, 578 (5th Cir. 1996) (citing *Coastal Corp.*, 869 F.2d at 819–20).

ANALYSIS

In its Preliminary Injunction Order, the Court carefully analyzed Propel's various articles, data, studies, and three days of testimony and determined that Propel's cited authority did not support the VPro5's advertising claims. Based on this finding, the Court enjoined Propel from advertising that the VPro5 provides its alleged 5 Clinical Benefits. Specifically, the Court prohibited Propel from "[r]epresenting, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial matter" that the VPro5 provides any of the 5 Clinical Benefits. Propel has filed an appeal to the Fifth Circuit on this matter. Propel now moves the Court to "modify" its Preliminary Injunction Order to allow Propel to publish various new data and studies that allegedly support that the VPro5 provides the 5 Clinical Benefits.

OrthoAccel argues that the "modification" Propel seeks would alter the status quo of the injunction and effectively divest the Fifth Circuit of its jurisdiction. The Court agrees. The Preliminary Injunction Order prohibits Propel from commercially disseminating materials making the enjoined claims. Propel asks the Court to "modify" the injunction so Propel *can* commercially disseminate materials that make the enjoined claims. Such "modification" would operate as a dissolution of the injunction because Propel asks the Court to allow exactly what the injunction enjoined—dissemination of materials alleging the VPro5 offers the 5 Clinical Benefits. The Fifth Circuit does not allow district courts to "alter[] the original injunction so that it no longer ha[s] any effect." *Sierra Club*, 73 F.3d at 578. "While the validity of an injunction is on appeal, the district court's power is limited to 'maintaining the status quo' pursuant to Rule 62(c) of the Federal Rules

of Civil Procedure." *Baum v. Blue Moon Ventures, LLC*, 513 F.3d 181, 190 n.2 (5th Cir. 2008) (citing *Coastal Corp.*, 869 F.2d at 820).

Even if the Court were able to determine that Propel's new studies and test did support that the VPro5 provides patients the 5 Clinical Benefits, the Court could not dissolve the injunction. In its appellate brief, Propel argues the Preliminary Injunction Order "prohibits Propel from disseminating additional proof of [the VPro5's alleged effectiveness] based on an unfounded assumption that it can never be true!" (Dkt. #298 at 37). If the Court were to "modify" its injunction to allow dissemination of Propel's new studies, it would moot the basis for Propel's challenge to the injunction. Federal Rule of Civil Procedure 62(c) "limit[s] . . . the district court's power to modify an injunction pending appeal, where the effect of its order would be to oust the appellate court's jurisdiction." *Coastal Corp.*, 869 F.2d at 819. The Court cannot "alter the status of the case as it rests before the court of appeals." *Id.* at 820.

Propel cites *Sierra Club* for the proposition that this Court should modify its Preliminary Injunction Order. *See Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.*, 73 F.3d 546 (5th Cir. 1996). In that case, the district court enjoined a party from discharging produced water into Galveston Bay "until such time as it secure[d] an NPDES permit for such discharges." *Id.* at 578. The district court modified its injunction to provide that discharge was permitted "so long as it complie[d] with the terms of said General Permit and Compliance Order." *Id.* The Fifth Circuit found the modification did not exceed "the district court's limited authority to alter an injunction to 'maintain the status quo.'" *Id.* Here, the Preliminary Injunction Order did not contemplate the Court periodically reassessing developments in Propel's research—a task that previously encompassed three days of cross-examined testimony and careful consideration of each of Propel's studies, tests, and data that allegedly supported the VPro5 could provide the 5 Clinical Benefits.

And the Court did not "*by its own terms* create[] the possibility for change in [the injunction's] operation." *Id.* at 579. Further, unlike *Sierra Club*, Propel seeks a "modification" that would greatly alter the status quo. *See id.* at 578 (holding the power to alter an injunction pending appeal is limited to "maintaining the status quo").

Propel argues that the Preliminary Injunction Order impinges on First Amendment rights because it restrains truthful speech. Propel cites a Second Circuit opinion that analyzes the Lanham Act's effect on the First Amendment to argue the Court should modify its injunction. *See ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 469 (2d Cir. 2013) (quoting *Keyishian v. Bd. of Regents of the Univ. of the State of N.Y.*, 385 U.S. 589, 603 (1967)) (cautioning against "overextension of the Lanham Act to intrude on First Amended values . . . when applying defamation and related causes of action to academic works, because academic freedom is 'a special concern of the First Amendment'"). But the Fifth Circuit has held that "[a]dvertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate." *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014). In *Eastman*, the Fifth Circuit recognized "[d]issemination of a scientific article as part of a company's marketing campaign is for promotional purposes and therefore qualifies as commercial speech," and found the First Amendment "does not immunize false or misleading commercial claims." *Id.* at 237 (citations omitted). Thus, the Court finds Propel's First Amendment concerns are unwarranted.

CONCLUSION

It is therefore **ORDERED** that Defendant Propel Orthodontics, LLC's Emergency Motion to Modify the Court's Preliminary Injunction Order (Dkt. #318) is hereby **DENIED**.

SIGNED this 2nd day of May, 2017.

AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE